

## **EPA Backs Strict Non-Cancer Protections In Draft TCE Risk Assessment**

**Inside EPA, 7/13/2009**

EPA is backing strict non-cancer safety standards to protect against exposure to the ubiquitous solvent trichloroethylene (TCE), according to a long-awaited draft risk assessment the agency has floated to other federal agencies for comment, sources familiar with the document say.

The new draft assessment -- which regulators will eventually use to set cleanup and other regulatory levels -- contains cancer and noncancer risk levels similar to those EPA's Superfund office released in an interim toxicity value for vapor intrusion cleanups shortly before the Bush administration left office, according to a federal agency source.

The Jan. 15 interim guidance -- which the Obama administration withdrew to resolve concerns about its non-cancer values -- recommended using California EPA's inhalation risk value of  $2 \times 10^{-6}$  micrograms per cubic meter of air (ug/m<sup>3</sup>) and oral cancer slope factor of 0.013 milligrams per kilogram of body weight per day (mg/kg/day) "for evaluating the carcinogenic effects of TCE in site-specific risk assessments."

But on non-cancer risks, the guidance document referenced both a California EPA chronic reference exposure level of 600 ug/m<sup>3</sup> and a New York Department of Health air criterion of 10 ug/m<sup>3</sup>, which the guidance "identified as two values that can be considered in evaluating systemic toxicity at sites."

One source said at the time the guidance was withdrawn for further review because EPA regions were concerned about the wide range between the two values and preferred the agency to adopt New York's stricter value.

The federal source says EPA's draft risk assessment "settled on a noncancer value closer to the" lower of the two noncancer numbers included in the guidance.

The new draft assessment is intended to replace a draft assessment EPA released in 2001 that was widely criticized as too conservative, with a cancer risk level up to twenty times that which EPA set in its first Integrated Risk Information (IRIS) assessment of TCE in the 1980s. The methodology underlying the assessment was reviewed by the National Academy of Sciences (NAS).

The values in the new draft assessment remain less conservative than those that EPA developed in its 2001 draft. For its 2001 cancer estimates, EPA developed slope factors predicting a risk between  $4 \times 10^{-1}$  and  $2 \times 10^{-2}$  per mg/kg/day, a slope more steep, or predicting more cancer risk, than the newest draft. On the noncancer side, EPA proposes a 2001 inhalation reference concentration -- or the amount of TCE that could safely be inhaled daily -- of  $4 \times 10^{-2}$  mg/kg-d.

The new draft's cancer potency values are based on data showing the kidney as the target organ of concern, as recommended by the NAS in its 2006 report, *Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues*, an industry source says. NAS recommended EPA and other "federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously," according to the report.

But the non-cancer assessment is drawing concerns from industry sources who are questioning what they understand is the basis for the agency's strict safety standards to protect against TCE's non-cancer health effects. New York's non-cancer standard for TCE "is based on heart malformation" studies, a consultant says.

Industry sources say they are concerned EPA is relying on studies showing TCE exposures can cause heart defects, which the industry sources say are not reliable. "The cardiac anomaly data -- there's nothing really there," one industry source says. Industry representatives and consultants who met with EPA in 2003 on the subject presented evidence that the heart defect data was not related to TCE exposure, and instead that the studies indicating this were poorly performed, an industry source says.

The industry argument was based on an analysis of 16 epidemiological studies of women likely exposed to TCE or similar chemicals while pregnant in various locations across the United States, and published in *Reproductive Toxicology* in 2005 by consultants with Mitretek Systems and an Air Force scientist.

The analysis concluded that "no single process [leading to a defect] was clearly affected by TCE, providing support that gestational TCE exposure does not increase the prevalence of" congenital heart defects, and noted a background incidence of such heart defects: nearly one percent of babies are born with them.

The industry source says that after the 2003 meeting, EPA staff agreed that the cardiac data "didn't matter," but since then, new studies have been published which may have convinced agency staff otherwise, the source says. The source, however, dismissed the newer studies as "sounding sophisticated and meaningful but [they're] probably not."

Meanwhile, California EPA's Office of Environmental Health Hazard Assessment (OEHHA) released July 9 its final public health goal (PHG) for TCE in drinking water, of 1.7 parts per billion (ppb). The number is less stringent than the state's previous 0.8 ppb standard, published in 1999. OEHHA derived the new standard from the same studies of cancerous tumors in mice that it used in the 1999 standard,

California also calculated a new "health protective value for noncancer toxicity" in the PHG as well, of 1 part per million. The standard is based not on heart defects but instead on a study of kidney abnormalities in rats. Existing California and federal Maximum Contaminant Levels for TCE in drinking water allow 5 ppb, "based on cancer risk," according to the PHG. -- *Maria Hegstad*